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No. 92-800

IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,

v.

KATHLEEN E. LES; FRANCES LES THOMAS;
MANUEL JESUS PEREZ MORALES; DAVID R. PEREZ;
MANUEL R. PEREZ,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* AND BRIEF *AMICUS CURIAE* OF THE AMERICAN FARM BUREAU FEDERATION IN SUPPORT OF PETITIONER

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MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* OF THE AMERICAN FARM BUREAU FEDERATION

The American Farm Bureau Federation respectfully moves for leave to file the attached brief *amicus curiae*, pursuant to Supreme Court Rule 37. Consents from Petitioners and Respondent United States are attached hereto. Consent was refused from individual and organizational respondents.

MOTION OF AMICUS CURIAE

The American Farm Bureau Federation (AFBF) is a not-for-profit, voluntary, general farm organization incorporated under the laws of the State of Illinois. Its purposes are to promote, protect and represent the economic, social and educational interests of farmers and ranchers across the United States. The largest general farm organization in the country, AFBF has member state organizations in all 50 states and Puerto Rico, representing the interests of more than 4 million member families.

Farm Bureau members have a direct and vital interest in the outcome of this case. Federally registered pesticides play an important and integral role in production agriculture by protecting crops from damage or destruction caused by pests and weeds. Nearly all of the fungicides necessary to keep these commodities disease-free will be canceled as a result of the Ninth Circuit's rigid application of the Delaney Clause. The loss of these and other registered products will have a substantial adverse economic impact on growers of agricultural commodities, especially those who produce fruits and vegetables. Many of these growers—Farm Bureau members—will be forced out of business if the means to protect their growing crops are taken away from them.

At the same time, Farm Bureau recognizes that the use of registered products cannot and must not compromise the quality or the safety of the good that is produced.

The decision below threatens both of these interests. Failure to consider the negligible degree of risk of certain pesticides will result in the loss of many pesticides that are necessary for crop protection. Furthermore, due to the unique place occupied by the Delaney Clause in the scheme of pesticide regulation, its strict application could actually result in the use of products that pose a

greater threat of cancer. That is due in part to the fact that pesticides that do not concentrate in processed foods and which do not come under the Delaney Clause might be more harmful than those which do come under it. Also, the failure to consider the degree of risk has prevented the registration of safer, lower risk pesticides and discouraged the production of others.

WHEREFORE, Applicant American Farm Bureau Federation respectfully prays that its Motion for Leave to file the attached Brief *Amicus Curiae* in favor of the Writ of Certiorari be granted.

Respectfully submitted,

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Dated: January 13, 1993

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BRIEF *AMICUS CURIAE* OF THE AMERICAN FARM BUREAU FEDERATION IN SUPPORT OF PETITIONER

INTEREST OF AMICUS CURIAE

The American Farm Bureau Federation (AFBF) is a not-for-profit, voluntary, general farm organization incorporated under the laws of the State of Illinois. Its purposes are to promote, protect and represent the economic, social and educational interests of farmers and ranchers across the United States. The largest general

farm organization in the country, AFBF has member state organizations in all 50 states and Puerto Rico, representing the interests of more than 4 million member families.

Farm Bureau members have a direct and vital interest in the outcome of this case. Federally registered pesticides play an important and integral role in production agriculture by protecting crops from damage or destruction caused by pests and weeds. At the same time, Farm Bureau recognizes that the use of registered products cannot and must not compromise the quality or the safety of the food that is produced.

The decision below threatens both of these interests. Failure to consider the negligible degree of risk of certain pesticides will result in the loss of many pesticides that are necessary for crop protection. Furthermore, due to the unique place occupied by the Delaney Clause in the scheme of pesticide regulation, the strict interpretation by the Ninth Circuit could actually result in the use of products that pose a greater threat of cancer. That is due in part to the fact that pesticides that do not concentrate in processed foods and which do not come under the Delaney Clause might pose a greater risk than those which do come under it.[1] Also, the failure to consider the degree of risk has prevented the registration of safer, lower risk pesticides and discouraged the production of others.

Through the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA), Congress has accommodated the need for pesticide products in the production of food and the concerns over food safety by enacting a regulatory scheme that balances the benefits of use of the product with the potential risks. When it was enacted, the De-

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[1] *Regulating Pesticides in Food: The Delaney Paradox*, National Academy Press, 1987 p. 85.

laney Clause was a powerful reinforcement of that balance. However, a much better understanding of cancer and its risks, combined with an exponential increase in the ability to detect traces of a substance to the lowest levels during the intervening 35 years has radically changed the place of the Delaney Clause in this balancing scheme. Instead of reinforcing that balance, it now obstructs it.

WHY THE WRIT SHOULD BE GRANTED

This case presents an important issue: how does a federal agency perform its regulatory mission when faced with a legislative provision that conflicts with the rest of an overall regulatory scheme and which has become inconsistent with the intent of Congress? The Ninth Circuit said that the language must be blindly followed, regardless of its effect.

We submit that federal agencies should be accorded some flexibility to consider advancements in science and technology in its administrative and rule-making processes. "Courts (and agencies) are not, of course, helpless slaves to literalism." *Public Citizen v. Young*, 831 F.2d 1108, 1112 (D.C. Cir. 1987). A *de minimis* interpretation provides that flexibility without compromising the regulatory mission of the agency. In this case, the issue is all the more important because the regulatory provision at issue has not only become outdated, but its age has made it inconsistent with the rest of the regulatory statute of which it is a part. Hanging in the balance is the fate of a number of widely used and safe pesticides which are necessary for farmers and ranchers to produce an economically viable crop.

Specifically at issue in this case is the Delaney Clause, codified at section 409 of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 348(c)(3)(A)]. The Food, Drug and Cosmetic Act (FFDCA) together with the Federal Insecticide, Fungicide and Rodenticide Act

(FIFRA) provide the statutory basis for the regulation of pesticides in the United States.

I. THE NINTH CIRCUIT'S RIGID INTERPRETATION OF THE DELANEY CLAUSE IS INCONSISTENT WITH THE STATUTORY SCHEME OF PESTICIDE REGULATION AND HINDERS THE ENVIRONMENTAL PROTECTION AGENCY IN THE PERFORMANCE OF ITS PESTICIDE REGULATORY MISSION.

"Congress enacted the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to regulate the use of pesticides in this country." *Defenders of Wildlife v. Administrator*, 882 F.2d 1294 (8th Cir. 1989). Of primary interest here is the fact that FIFRA regulates the registration, use, labeling and cancellation of pesticides in the United States.

FIFRA provides a balancing test in the registration and cancellation of pesticides. A pesticide will be registered if "it will perform its intended function without unreasonable adverse effects on the environment." 7 U.S.C. 136a(5). Similarly, the Administrator of EPA may cancel a pesticide use if he determines that the pesticide "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." 7 U.S.C. 136d(b). "Unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb). In both cases, therefore, the benefits of a pesticide are weighed against the possible risks to determine whether a pesticide should be registered or canceled.

Where FIFRA directly regulates pesticides through functions such as registration and cancellation, FFDCA regulates pesticides in a more indirect way. It provides

for the establishment of maximum concentrations of pesticide residues ("tolerances") in both raw agricultural commodities and in processed foods. The Environmental Protection Agency (EPA) has the responsibility for establishing and administering these tolerances under FFDCA.

Section 408 of the FFDCA [21 U.S.C. 346a] governs the establishment of tolerances for pesticide residues on raw agricultural commodities. Raw agricultural commodities containing pesticide residues that either exceed the established tolerance, or for which no tolerance has been set, are deemed "adulterated" under the FFDCA and are subject to seizure. Section 408 requires that these tolerances be set at levels deemed necessary to protect public health, while at the same time considering the need for "an adequate, wholesome, and economical food supply." (21 U.S.C. 346b). Like FIFRA, section 408 explicitly provides for the consideration of both the risks and the benefits of a particular pesticide in the setting of tolerances.

Section 409 of FFDCA [21 U.S.C. 348] governs the establishment of tolerances on certain processed foods, and contains the Delaney Clause which is at issue in this case. Section 409 provides tolerances for "food additives," and does not directly mention pesticide residues. The Delaney Clause [21 U.S.C. 348(c)(3)(A)] provides that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." Unlike the registration/cancellation provisions of FIFRA and FFDCA section 408 described above, section 409 strictly applied, does not allow the balancing of risks and benefits in deciding whether or not to issue a tolerance.

Of the major pesticide regulatory provisions, only section 409 with the Delaney Clause employs an absolute

standard rather than a balancing of risks and benefits. Thus, pesticides that pass all the registration criteria of FIFRA and the criteria for obtaining a tolerance under section 408, might be denied a section 409 tolerance on processed foods as a result of the strict application of the Delaney Clause.

But that is not the end of the internal inconsistencies caused by the Delaney Clause. EPA regulations provide that EPA will not register a pesticide for raw agricultural commodities if a section 409 tolerance is required but cannot be obtained because of the Delaney Clause [40 CFR 152.112(g)]. Presumably, if pesticides are later found to induce cancer in humans or in animals they would lose any section 409 tolerance, which would result in the cancellation of the product.

This application of Delaney goes beyond mere inconsistency. It subverts the entire foundation of the pesticide registration/cancellation system established in FIFRA, and also completely undercuts the procedure by which section 408 tolerances are established. In the process, this interpretation of Delaney has ignored the intent of Congress as expressed in both FIFRA and section 408 of the FFDCA.

II. MODERN TECHNOLOGY AND SCIENTIFIC ADVANCES HAVE MADE RIGID ADHERENCE TO THE DELANEY CLAUSE UNNECESSARY.

The swift emergence of new technology and advances in science, when combined with the inherent conflict of Delaney with the pesticide regulatory framework, makes the Ninth Circuit's interpretation of Delaney both inconsistent and counter-productive.

The food additive Delaney Clause was enacted in 1958 —almost thirty-five years ago. Much has changed on the scientific landscape since then. In 1958, scientists were able to detect substances only down to parts per million. Today, substances can be measured at one part per trillion, or lower. Such technological advances have made

a tremendous difference in how risks are assessed and measured. Substances found at levels of parts per million might pose significant health risks to humans or animals, while the same substances found at parts per trillion may pose only a very slight health risk or none at all.

Not only does this modern technology allow the detection of much greater numbers of substances in much smaller amounts, it also permits EPA to assess risks to a much more sophisticated degree. Thus, EPA is now able to determine that certain risks are either "negligible" or "significant," where, as in the past, these risks could not be differentiated. To show how much has changed since the Delaney Clause was enacted, the entire discussion of *de minimis* risks could not have taken place in 1958 because science had not yet been able to define *de minimis* risks in this context. The science of risk assessment itself has undergone significant change in the past several years, which also is enough to justify regulatory flexibility in interpreting the Delaney Clause.

In today's world, the Ninth Circuit's strict interpretation of the Delaney Clause has potentially negative impacts on the food supply and on human health. The Ninth Circuit's interpretation of the Delaney Clause prevents the registration of new, less oncogenic pesticides in favor of pesticides in use before 1978 and which, by EPA comparison, are more toxic. These older pesticides were subject to less stringent testing requirements for registration, a condition which changed in 1978.[2] The National Research Council estimates that more than 80% of the risk of cancer from processed foods comes from pesticides with tolerances granted prior to 1978.[3] Research into newer, safer pesticides that pose very minimal

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[2] *Regulating Pesticides in Food: The Delaney Paradox*, National Academy Press, 1987 p. 85.

[3] *Id.*

risks of cancer are being discouraged by strict application of the Delaney Clause.

Another factor, reflecting the inherent inconsistency between section 408 and 409, causes unintended adverse effects as a result of the Ninth Circuit's interpretation of the Delaney Clause. Processed foods with pesticide residue levels at the same or lower levels as the same section 408 tolerance for raw agricultural commodities are exempt from section 409 tolerances. FFDCA section 402 (a) (2) (C) provides this exemption on the theory that if such residues are safe for raw commodities under section 408, they are also safe in processed foods. Section 409 and the Delaney Clause only involve pesticides which concentrate in processed foods to a degree greater than on raw commodities.

This means that the critical factor for determining section 409 tolerances is not the safety of the pesticide, but whether or not it concentrates in processed foods. Pesticide residues with section 408 tolerances that might induce cancers are nevertheless free of section 409 tolerance requirements if the residues do not concentrate in processed foods.

The Ninth Circuit's view of the Delaney Clause in today's technology would subvert the real purpose of the FFDCA and the original purpose of the Delaney Clause itself. It permits older pesticides to remain on the market at the expense of newer, safer pesticides. More importantly, it discourages research and development of newer, safer pesticides that might not pass the strict zero-risk criterion of the Delaney Clause. All of these factors make it more difficult for EPA and the Food and Drug Administration to carry out their mission to ensure a safe food supply. By contrast, the *de minimis* interpretation advanced by EPA is a reasonable response to the new challenges brought on by this new science. It allows EPA to take advantage of the new technology to more responsibly perform its regulatory mission.

III. THE NINTH CIRCUIT'S RIGID APPLICATION OF THE DELANEY CLAUSE WILL HAVE SERIOUS ADVERSE CONSEQUENCES TO OUR NATION'S FOOD PRODUCTION.

The Ninth Circuit strict application of the Delaney Clause will result in the loss of many pesticides that are necessary for the production of certain crops. The impacts are most likely to be felt during the re-registration process when EPA requires updated data about these pesticides.

EPA contends that section 408 tolerances for fresh agricultural commodities are tied to section 409 tolerances and the Delaney Clause for processed foods. Thus, both commodities produced for the fresh market as well as for processing will be heavily impacted by the Ninth Circuit decision.

Hardest hit will be the so-called "minor use crops," which are typically grown on limited acreage and have a limited market. This category includes all fruits and vegetables, which comprise about 20% of the diets of American consumers. These commodities are vital nutritional components of a person's diet. Study after study has revealed that a diet rich in fruit and vegetables can reduce the risk of heart disease, cancer, and obesity.[4]

The limited market for these pesticides already makes it unattractive for pesticide manufacturers to incur the cost of registration or re-registration of products where the profits are limited. The present suit involves only four products. There are, however, more than 50 widely used products which show some evidence of carciongenicity that will be affected if the Ninth Circuit decision stands.

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[4] "Eat Vegetables for Health's Sake," *American Vegetable Grower* Magazine, Winter 1991 Special Issue, p. 16. It is ironic that a statute designed to prevent the spread of cancer might result in the loss of production of the food products that, when eaten, are most effective in reducing the risk of cancer.

Since many fruits and vegetables are processed as well as fresh, they come under section 409 and the Delaney Clause. Most fungicides used in the production of these crops would be canceled under the decision below, and their loss would result in serious adverse impacts to the growing of fruits and vegetables. Fungicides are necessary to control disease on fruits and vegetables, especially in warm, wet growing areas of the country. The impacts would be most dramatic and severe for fruits and vegetables produced east of the Mississippi River, where temperatures, rainfall and humidity are all high. Florida is the nation's second largest fruit and vegetable producer, and would be hardest hit by the loss of these products. Michigan and Wisconsin are two other major producing states that will be adversely impacted as well.

Without denfiing what it means by carcinogenicity or how it arrived at its conclusions, EPA has alleged that the five most widely used fungicides on fruits and vegetables (Captan, Chlorothanonil, Benomyl, Mancozeb and Maneb) all show some evidence of carcinogenicity.[5] Their loss would especially adversely impact the growing of potatoes, apples, peaches and tree fruits.

In many cases, there are no available alternatives to prevent disease on commodities like cranberries, asparagus and rhubarb.

Two major insecticides—Phosmet and Azinphos-methyl —heavily used on fruits and vegetagles would also be lost if the decision is allowed to stand.

Even if only section 409 tolerances are affected, there will still be major agricultural repercussions. Many growers, especially in California, grow exclusively for processors under contract, and they would be forced out of business by the Ninth Circuit decision. The same circumstances would apply, for example, to producers of

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[5] 53 Red. Reg. 41104 (Oct. 19, 1988).

corn in Wisconsin and Minnesota who also grow under contract. Without the necessary chemicals, these crops would not pass quality or mold standards, and their introduction in the food supply would result in less safe food. Most of this production would move outside the United States and return in processed form. This would serve to further weaken our balance of trade and our position within the world economy.

The fresh market would also be affected under this scenario. Currently, most fresh fruits and vegetables that do not meet fresh standards are processed. Elimination of the section 409 tolerances for the pesticides at issue would also eliminate this practice, making it much more difficult for producers to dispose of such products. Consumers will not accept fruits and vegetables that are bruised, misshapen or damaged. Yet the products at issue here are the very tools to prevent those situations from happening.

There is little likelihood that there will be any alternatives or replacements for those canceled fungicides under current regulatory conditions. Manufacturers, already inhibited from investing large sums of money into research and development for pesticides on minor use crops, will be even less likely to invest money necessary to obtain a registration if registration will be precluded by the decision below.

IV. THE DE MINIMIS INTERPRETATION OF THE DELANEY CLAUSE BY EPA IS A REASONABLE REGULATORY RESPONSE.

In light of the fact that internal legislative inconsistencies and modern science has put the Delaney Clause at odds with the goal of maintenance of the safest food supply possible, EPA adopted its *de minimis* interpretation of the Delaney Clause.

The Court has recently reaffirmed its acceptance of *de minimis* exceptions to seemingly-absolute statutory pro-

visions in *Wisconsin Department of Revenue v. Wrigley*, 112 S.Ct. 2447 (1992). This standard allows some reasonable exceptions to a statute which "operates in such stark, all-or-nothing fashion." *Id.* at 2458. This principle is as applicable to the "stark, all-or-nothing" language of the Delaney Clause as it was to section 381 of the Internal Revenue Code in *Wrigley*.

Adoption of a *de minimis* standard is especially appropriate where, as here, the statutory provision is inconsistent with the rest of the regulatory program. Thus, "notwithstanding the 'plain meaning' of a statute, a court must look beyond the words to the purpose of the act where its literal terms lead to 'absurd or futile results.'" *Alabama Power Co. v. Costle*, 636 F.2d 323, 360 (D.C. Cir. 1980). "Imposition of pointless burdens of regulated entities is obviously to be avoided if possible." *Id.* p. 360-361.

As indicated above, the Ninth Circuit's reading of the Delaney Clause could lead to "absurd or futile results." Pesticides that do not concentrate in processed foods that pose a greater cancer risk will be forced to be used in place of pesticides that concentrate in processed foods and which have a slight or negligible risk of cancer. Pesticides registered prior to 1978 will be prefererd over subsequently registered pesticides, even though the latter pesticides pose less of a risk. This leads to the "absurd result" that cancer risks would be greater by application of the very provision whose purpose it was to prevent concer in foods. Adoption of a *de minimis* interpretation was necessary to bridge the growing gulf between the intent of the regulatory scheme and the original Delaney Clause and to bring them into harmony.

A *de minimis* interpretation reduces these conflicts, permits EPA to perform its regulatory mission in a systematic manner, and protects both the safety of American grown food supplies and the economic viability of agricultural production.

But the Ninth Circuit never addressed the question whether the *de minimis* doctrine as applied to the Delaney Clause was reasonable. Instead the court became one of those "helpless slaves of literalism" that ducked an important health issue. In so doing, the Ninth Circuit erroneously invoked the holding in *Public Citizen v. Young, supra,* to justify its result that the *de minimis* doctrine did not apply in this case.

Public Citizen interpreted a provision similiar to the food additive Delaney Clause—the color additive Delaney Clause (21 U.S.C. 376). The D.C. Circuit determined that the rigid language of that clause did not permit a *de minimis* interpretation. While this is the same result as that arrived at by the Ninth Circuit, the anlysis used in *Public Citizen* might have produced a different result in this case. In fact *Public Citizen* expressly states that "Although the two clauses have almost identical wording, the context is clearly different." *Public Citizen, supra* at 1120. As a result, the D.C. Circuit said that for the issues decided by the Ninth Circuit, "their answer is not foreordained by our decision here." *Id.* at 1120.

For the D.C. Circuit, the difference between the two provisions seems to be the differnce supply in importance between color additives and food additives such as pesticides. The court examined the legislative history of the color additive provision, and concluded that:

> there is evidence that Congress thought the public could get along without carcinogenic colors, especially in view of the existence of safer substitutes. Thus the legislators may have estimated the costs of an overly protective rule as trivial.[6]

The perception of the food additive Delaney Clause by the court was quite different, saying: "Without having canvassed the legislative history of the food additive Delaney Clause, we may safely say that its proponents

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[6] *Public Citizen, supra* at 1117.

could not have regarded as trivial the social cost of banning those parts of the American diet that CTFA argues are at risk." *Public Citizen, supra*, at 1120.

In a sense, the court in *Public Citizen* performed a quick risk/benefit analysis to determine the possible costs resulting from a strict interpretation of the color additive Delaney Clause. Finding that Congress perceived little cost, it held that strict interpretation was meant.

No such analysis or examination of legislative history was performed by the Ninth Circuit. At stake here is the viability of more than 20% of the diet of most Americans, including most of the sources of Vitamin C and beta-kerotene. We submit that this issue is deserving of at least the same type of analysis applied in *Public Citizen*, as to whether a *de minimis* interpretation to the food additive Delaney Clause is a reasonable response to the protection of the health of consumers and the safety of America's food supply.

CONCLUSION

Advancements in science and new technology have reduced the utility and effectiveness of the food additive Delaney Clause within the overall pesticide regulatory framework. Indeed, the Ninth Circuit's interpretation of the Delaney Clause is actually counter-productive to the regulatory mission of EPA and FDA to assure a safe and healthy food supply. The Delaney Clause favors older, more toxic pesticides and those that do not concentrate in processed foods over newer and safer pesticides. In addition, the Ninth Circuit's interpretation of the Delaney Clause threatens the viability of the foods that are most effective in reducing cancer risks.

All of these factors hamper the efforts of EPA and FDA to perform their regulatory functions. In an effort to harmonize the Delaney Clause with the pesticide regulatory framework, the EPA, consistent with accepted canons of construction of similar all-or-nothing statutes,

proposed use of a *de minimis* application of the Delaney Clause.

The opinion below failed to consider this unique situation, and the reasonableness of the *de minimis* interpretation as a response to it. We submit that the issues presented are of such importance that they should be considered by this Court. For these reasons, the writ of certiorari should be granted.

Respectfully submitted,

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